SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

INOTYOL, ointment

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Ichthammol..... 1.474 g

Zinc oxide..... 14.763 g

Hamamelis..... 0.984 g

Siam benzoin..... 0.100 g

Titanium dioxide..... 5.905 g

For 100 g of ointment.

Excipients with known effect: wool fat, alcohol, essential oil of lavender containing limonene, linalool and terpene derivatives (see section 4.4).

For a full list of the excipients, see sections 6.1.

3. PHARMACEUTICAL FORM

Ointment.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

Local treatment of eczema, feet ulcers, mild burns and skin irritations.

4.2. Posology and method of administration

Apply as a thick layer 2 or 3 times daily.

4.3. Contraindications

- Known hypersensitivity to any of the ingredients,
- Infected or weeping dermatitis,
- children with a history of convulsions, febrile or otherwise (due to the presence of terpene derivatives as excipients).

4.4. Special warnings and precaution for use

Special warnings

This medicine contains terpene derivatives as excipients, which can lower the seizure threshold. At excessive doses, risk of neurological accidents such as convulsions in infants and children.

Follow the doses and the recommendations for use. In particular, do not apply to a large surface area of the body.

This medicine contains 0.15 g of alcohol per 50 g tube.

In neonates, high concentrations of ethanol may cause severe local reactions and systemic toxicity due to significant absorption through immature skin (especially under occlusion).

This medicine contains wool fat and can cause local skin reactions (for example, contact dermatitis).

This medicine contains fragrance containing limonene and linalool which may cause allergic reactions. In addition to allergic reactions in sensitised patients, non-sensitised patients may become sensitised.

Precautions for use

In the event of a history of epilepsy, take into account the presence of terpene derivatives as excipients.

4.5. Interactions with other medicinal products and other forms of interaction

The data available to date do not suggest the existence of any clinically significant interactions.

4.6. Fertility, Pregnancy and lactation

Pregnancy

There are no data available relating to the use of Inotyol in pregnant women. As a precaution, it is preferable to avoid using Inotyol during pregnancy.

Lactation

If breast-feeding, this medicine should not be used because:

- the absence of kinetic data on the passage of terpene derivatives in milk,
- and their potential neurological toxicity in infants.

4.7. Effects on the ability to drive and use machines

Not applicable.

4.8. Undesirable effects

Risk of sensitisation to any of the ingredients (Lanolin/wool fat, benzoin, etc.).

Due to the presence of terpene derivatives, as excipients, and in the event of non-compliance with the recommended doses:

- risk of convulsions in infants and children,
- possibility of agitation and confusion in the elderly.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.

Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form at: https://sideeffects.health.gov.il.

Additionally, you can also report to: Padagis.co.il.

4.9. Overdose

In the event of overdose, risk of neurological accidents such as convulsions in infants and children and possibility of agitation and confusion in the elderly.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Pharmacotherapeutic group: SKIN PROTECTIVE, ATC code: D. Dermatology.

5.2. Pharmacokinetic properties

Not indicated.

5.3. Preclinical safety data

Not indicated.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Wool fat, Light liquid paraffin, White soft paraffin, Lavender oil, Ethanol anhydrous **or** Ethanol 96%, purified water.

6.2. Incompatibilities

Not applicable.

6.3. Shelf-life

The expire date of the product is indicated on the packaging materials.

Shelf life after first opening: 6 months

6.4. Special precautions for storage

Store below 25°C

6.5. Nature and contents of the container

50 g sealed aluminium tube, closed with a white polypropylene cap.

6.6. Specials precautions for disposal and handling

No special requirements.

7. REGISTRATION HOLDER

Padagis Israel Agencies Ltd.

Rakefet 1, Shoham, 6085000, Israel

8. MARKETING AUTORISATION NUMBER(S)

022.26.21121

Revised in January 2023 according to MOH guidelines.